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EXAMINER	
RIGGINS, PATRICK S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,431	UNSICKER ET AL.	
	Examiner	Art Unit	
	Patrick S. Riggins	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/16/04, 12/22/04, and 3/31/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *6,15-22,24 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, drawn to protein containing compositions, in the reply filed on 7/16/04 is acknowledged. The traversal is on the ground(s) that applicant's amendment to the claims has overcome the finding that the special technical feature is anticipated by Peulve and Johnson (both of record) and thus the claims lack unity. This is not found persuasive because although the amendment to the claims has specified GDF-15 as the protein that is encoded by the nucleic acid this feature is still found to lack novelty. WO97/00958 (of record) discloses a TGF-β like cytokine which shares sequence identity with GDF-15 protein and only silent mutations with respect to GDF-15 cDNA (see Figure 1). Therefore, the newly amended claims still lack unity.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 15-22, 24, and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/16/04. It is acknowledged that claim 6 was initial listed as residing in Group II however as claim 6 is clearly drawn to nucleic acid sequence it is drawn to a non-elected invention and is withdrawn.

3. Currently claims 1-26 are pending with claims 1-5, 7-14, 23, and 25 as drawn to a pharmaceutical composition comprising GDF-15 protein, are currently under examination.

Specification

4. Amendments to the specification filed 12/22/04 and again filed 3/31/05 are acknowledged.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The corrections made in the amendments filed 12/22/04 and 3/31/05have corrected certain deficiencies with respect to sequence compliance. The following locations in the specification have been noted that refer to sequences, but do not, as required, identify those sequences by SEQ ID NO. The non-appropriately annotated references to sequences can be found in the paragraph bridging pages 3-4, the paragraph beginning on line 24 of page 4, and the paragraph starting on line 20 of page 9, which though partially corrected by adding reference to SEQ ID NO:5, still requires reference to SEQ ID NOs:1 and 3.

6. The disclosure is objected to because of the following informalities: A heading --Brief description of the Drawings-- is required on page7. Further each figure must be identified individually. Changing the figure legend labels to --Fig. 1A-1D--, --Fig. 4A-4B--, Fig.5A-5B--, Fig. 6A-6B--, --Fig. 7A-7B--, and --Fig. 8A-8B-- would be remedial.

Appropriate correction is required.

Claim Objections

7. Claims 1, 3, 5, 9, 10, and 25 objected to because of the following informalities: When acronyms are to be used in the claims they should be explicitly stated at least the first time they appear. Claim 1 recites "DAergic", claim 4 recites "NO", claim 10 recites CNS, and claim 25 recites NO and CNS. It is noted that correction of claims 4 and 10 in this regard would obviate the objection of claim 25. Claim 1 is currently drawn to non-elected inventions. Claim 25 is also drawn to non-elected inventions, comprising the limitations of claim 6. To amend these claims to eliminate reference to the non-elected inventions would be remedial. Claim 3 recites "protein GDF-15 protein", which contains improper grammar. Deletion of the first instance of "protein" would be remedial. Claim 9 appears to be an attempt at Markush style language. Reciting "and/or" in this context is improper. See MPEP 2173.05(h). Appropriate correction is required.

8. Claims 3, 9-11 and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is drawn to a pharmaceutical composition for the prevention or treatment of neurodegenerative disorders. Claim 3 recites that GDF-15 "protects against neurodegenerative events". This fails to further limit because if one successfully treats a neurodegenerative disorder, one must necessarily protect against neurodegenerative events, thus the limitation is inherent. Claim 9 places the limitation that the neurodegenerative disorders can be psychological disorders, claim 10 further limits to, among other things, stroke, and "psychiatric disorders associated with disturbances in CNS transmitter systems" which claim 11 further limit as depression or schizophrenia. Claim 25 contains these same limitations. Psychological disorders, stroke and especially the psychiatric disorders defined

are not neurodegenerative disorders. The limitations themselves acknowledge this specifically limits psychiatric disorders to those with transmitter imbalance. Stroke is a traumatic injurious event, while psychological and psychiatric disorders are generally due to an imbalance in neurotransmitter release or responsiveness. Thus, limitation to these diseases does not further limit the scope of the claims, but rather broadens the scope of the claims.

Claim Rejections - 35 USC § 112-2

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2, 4, 5, 9-11, 23, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 2 recites the limitation "pharmaceutical composition acid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 4 recites "mediators" with no reference as to what is being mediated or what variety of mediator is intended. As such the metes and bound of this limitation cannot be ascertained.

13. Claim 5 recites the limitations "mediators of the free radical damage" and "mediators ... of neuronal death programs". There is insufficient antecedent basis for these limitations in the claim.

14. Claims 9-11 place limitations that broaden the scope of the claims as described above. As such, the skilled artisan could not determine the metes and bounds of these claims. Are the claims drawn specifically to pharmaceutical compositions for the treatment of neurodegenerative

diseases, or are these other non-neurodegenerative diseases also intended to be included? As there is no further definition provided in the specification with regard to what is intended by "other dementias", the skilled artisan would have no way to determine the metes and bounds of this limitation.

15. Claim 25 is vague and indefinite because it depends from indefinite claim 2, it contains the limitation of undefined "mediators" as in claim 4, it contains terms that lack antecedent basis as in claim 5, it contains limitations that broaden the scope of the claims, as in claims 9-11, and the term "the agent" in the fourth line from the bottom, lacks antecedent basis.

Claim Rejections - 35 USC § 112-1

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-14, 23, and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *in vitro* protection of rat dopaminergic neuron from iron-induced cytotoxicity and enabling for treatment of the 6-OHDA rat model of parkinsons disease (PD) does not reasonably provide enablement for the prevention of neurodegenerative diseases or the treatment of any neurodegenerative disease in humans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

17. The claims are drawn to a pharmaceutical composition intended to be used for the prevention and/or treatment of neurodegenerative disorders in mammals. The mammal may be human. The neurodegenerative events can be mediated by oxidative damage, free radical

damage, mediators, and/or executors of neuronal cell death. The free radical mediators can be iron, NO donors or other free radical donors and the mediators and executors of cell death can be caspase or members of the bcl-2 family of proteins. The protein can be of a particular sequence. The neurodegenerative disorders can be acute and/or chronic neurological and psychological disorders, where the disorders can be cause by stroke, PD, Alzheimer's disease (AD), other dementias, infection of the CNS, or psychiatric disorders associated with alterations in neurotransmitter systems, which can be depression or schizophrenia. The composition can additionally comprise additional agents which can be particular cytokines. There is not sufficient guidance provided in the specification when combined with the level of knowledge in the art to enable the skilled artisan to treat this variety of diseases and mechanisms of disease without undue experimentation.

18. A number of factors have been considered in making this assertion that undue experimentation is required to practice this invention as delineated by *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

19. The claims are broadly drawn, as any neurodegenerative disorder may be the intended disease for treatment. In actually, the claims are broadened even further, as non-neurodegenerative diseases are also claimed, as described above. The specification provides examples where rat embryonic midbrain dopaminergic neurons had enhanced survival in the presence of GDF-15. GDF-15 was shown to rescue mesencephalic neurons from iron-

intoxication. GDF-15 was also shown to reduce dopaminergic neuron loss in the 6-hydroxydopamine (6-OHDA)-induced damage model of PD. There is no question with regard to the enablement of these embodiments. The question that arises, however is how applicable these findings would be in regard to other neurodegenerative diseases and whether these studies in rats are applicable to higher mammals, particularly humans.

20. As the teachings in the specification all address dopaminergic neurons, the question then turns to whether the variety of diseases named in fact are due to depletion of dopaminergic neurons. With PD, the answer is clearly yes, as the 6-OHDA model system used in rat is a recognized model for PD. What of the other diseases mentioned? AD is a multifaceted disease where the pathology is largely due to deposition of plaques and tangles. Many neurochemical pathways are involved, including the cholinergic system, the serotonergic system the noradrenergic system, the dopaminergic system, the glutamatergic system, and the GABAergic system, with the cholinergic system apparently the most pronounced. (see pages 266, 267, 272, 273, 276, and 280 of Gsell). "Functionally, by means of neurochemical findings, the disturbances are much more spread on different neuronal and biochemical systems. However, there seems to be a clear rank order with cholinergic neurotransmitter system showing more pronounced deficits than others" (Gsell Curr Pharm Des 10:265-293 (2004), newly cited, page 266, second paragraph). Thus, even though dopaminergic neurons may play some role in AD, it seems highly unlikely that strictly rescuing dopaminergic neurons in an AD patient would have a low likelihood of success.

21. Stroke, as defined by the Concise Dictionary of Biomedicine and Molecular Biology, is "sudden loss of consciousness and voluntary motion caused by rupture or obstruction of an artery of the brain due to the formation of an embolus or thrombus" (page 855). Thus, a stroke is not

specific to a particular variety of neurons, only those neurons that happen to be in close proximity to the rupture or obstruction event. Additionally, although neurons in the vicinity of a stroke may indeed be killed, this is not due to neurodegeneration, rather it is due to a traumatic incident. As a stroke is generally not a predictable event and as potential damage to dopaminergic neurons is not assured, it would seem highly unlikely that GDF treatment would have any clinical efficacy for treating a stroke.

22. Other dementias are not clearly defined, so the only way GDF-15 treatment may lead to any effect would be if those other dementias were as a result of dopaminergic neuron loss. No infections of the CNS are identified in the specification. Unless an infection led to the destruction of dopaminergic neurons, GDF-15 would be unlikely to have any impact on CNS infections because no evidence is provided to suggest that GDF-15 would protect from infection or negatively affect the infecting agent. Psychiatric disorders such as depression and schizophrenia are not due to neurodegeneration, but rather are due to "disturbances in CNS transmitter systems" as defined in claim 10. The specification teaches that GDF-15 leads to enhanced survival of dopaminergic neurons. As these diseases are not due to death of dopaminergic neurons, it seems highly unlikely that GDF-15 would have any clinical efficacy for treating these disorders. Thus it seems unlikely that GDF-15 would be useful for the treatment of any of the identified disease other that potentially PD.

23. This then lead to the question as to how reliably one can relate the data regarding treatment of 6-OHDA-treated rats to PD patients. Emborg discusses the relative merits of different animal models for studies pertaining to protection against PD (J. Neurosci. Methods 139:121-143 (2004), newly cited). Emborg states that: "Several models exhibit many of the characteristic features of the disease; however none mimics the complex chronic

neurodegenerative features of human PD" (page 123, first full paragraph). How effective then is the 6-OHDA system as a model? Table 2 on page 129 states that studying rotations as a measure of damage is useful because equipment is standardized and the assay is widely used, however, this method has "no clinical value" with "low sensitivity to small changes in striatal DA." Emborg does agree that the 6—OHDA system is useful for initial tests, "a single experiment does not provide the ultimate proof of neuroprotection and that clinically relevant data have behavioral, biochemical, and anatomical correlates" (First paragraph of Section 4, page 134). Indeed, Emborg states: "Evidence of neuroprotection in rodents does not ensure similar results in non-human primate models, probably due to monkey's bigger volume distribution and complexity of the CNS. Translation to PD patients may prove even more difficult" (page 134, column 1, third full paragraph). Clearly then effectiveness of an agent in the 6-OHDA assay in rats is not sufficient to ensure success in treating PD in human subjects.

24. What then of the possibility of preventing neurodegenerative disorders? In short this is nearly impossible as neurodegeneration takes place prior to presentation of clinical symptoms and prior to any diagnosis (DeKosky Science 302:830-834 (2003), newly cited, see page 830 and Figure 1). Thus to prevent disease, on would have to identify patients at risk for the disease prior to any neurodegeneration. This is impossible in our current state of technology and was certainly not possible at the time of filing.

25. When determining if an enablement rejection is proper, one first looks to the specification for teachings that would enable the skilled artisan to practice the invention. The instant specification provides guidance only with respect to treating 6-OHDA-treated rats, with no evidence of any efficacy in any other *in vivo* assay. If one determines that the specification itself is not enabling, one then looks to the art to determine if the knowledge existed in the art at the

time of filing that would have enabled one to practice the invention. As delineated above, there was no such knowledge in the prior art and in fact post-filing date references clearly establish that efficacy in the 6-OHDA rat model in no way assures success in treating higher mammals including humans. Further, it is clear simply from the timing required to prevent a neurodegenerative disorder that the skilled artisan would not know how to prevent a neurodegenerative disorder. Following the art determination one then considers the level of experimentation that would be required to practice the invention. As the art is highly unpredictable and insufficient guidance is provided in the specification, an undue level of experimentation would be required of the practitioner to carry out the full scope of the intended use for the claimed composition and as such the specification is not enabling.

Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

27. Claims 1-5, 6-11, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/00958 (hereinafter Breit, of record). The claims are all drawn to a pharmaceutical composition comprising GDF-15 protein, optionally in combination with a pharmaceutically acceptable carrier. The remainder of the limitations is all drawn to intended use. MPEP in 707.07(f) recites "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." Breit discloses both the full length sequence identified as SEQ ID NO:3 in the instant application and also discloses the cleavage product which is SEQ ID NO:4 (see page 3, lines 20-25, page 8, lines 7-8, page 11, lines 6-11 and 20-21, Example 3, and the sequence in Figure 1) dubbed pCL13 by Breit. The sequence disclosure of Breit further includes the additional 13 amino acids (SEQ ID NO:5) found in the paragraph starting on line 20 of page 9 of the instant application. Breit further discloses that the pCL13 can be combined with a suitable pharmaceutically acceptable carrier (page 4, lines 28-34).

28. Claims 1-5, 7-11, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bootcov (Proc. Natl. Acad. Sci. USA 94:11514-11519 (1997), of record). Bootcov discloses MIC-1 which is identical to GDF-15 and recognized the processed form of MIC-1, which is identical to SEQ ID NO:4 of the instant application (see Figures 1 and 3 and the paragraph bridging the columns of page 11516). The purified protein was mixed with a pharmaceutically acceptable carrier containing less than 0.01 endotoxin units/ml (page 11515, column 1).

29. Claims 1-5, 7-11, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,500,638 (hereinafter Hudson, newly cited). Hudson was filed 7/28/99, but has priority to a National Stage application with a National Stage entry date of 10/2/95. SEQ ID NO:2 of Hudson differs from SEQ ID NO:3 of the instant application by only two conservative amino acid substitutions: T-S at residue 35 and L-F at residue 281. The claims are anticipated by the claims. Specifically, reference claims 9, 17, 23, 42, and 53 are specifically drawn to compositions comprising the identified protein and a pharmaceutically acceptable carrier.

30. Claims 1-5, 7-11, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,180,602 (hereinafter Kato, newly cited). Kato discloses and claims a protein identical to the protein of the instant invention, i.e. SEQ ID NOs: 2 and 4 of Kato are identical to SEQ ID NOs:3 and 4 of instant application, respectively (see reference claims 1-3), with the slight caveat that reference SEQ ID NO:4 contains the additional 13 amino acid residues specified in the paragraph starting on line 20 of page 9 of the instant application. Additionally, Kato specifically claims a composition comprising the active form of the protein (reference claim 4).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. Claims 1-5, 7-14, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breit. Breit discloses the pharmaceutical composition as described above, but does not

disclose a composition comprising an additional neurotrophic agent which can be TGF. Breit discloses a variety of assays to test the function of pCL13, which again is identical to GDF-15, and compares the effects to those seen when the assays are performed in the presence of TGF-β (see Examples 11-16 and Figures12-19). Breit observed that pCL13 had very similar effects in all of the assays tested to TGF-β. As the two agents had similar effects in all assays tested, the skilled artisan would have had a reasonable expectation that treating with both pCL13 and TGF-β would lead to improved effects over those seen with either agent alone. Thus, the skilled artisan would have been motivated to treat the cells in the various assays of the examples with a composition comprising both pCL13 and TGF-β. The skilled artisan would have found it obvious to utilize a composition comprising pCL13 and TGF-β.

33. Claims 1-5, 7-14, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bootcov. Bootcov discloses the composition as described above, but does not disclose a composition comprising an additional neurotrophic agent which can be TGF. Similar to Breit, Bootcov discloses assays utilizing either MIC-1, which again is identical to GDF-15, or TGF-β and found that MIC-1 and TGF-β had similar effects on TNFα production. As argued above, it would have been obvious to one of ordinary skill in the art to use a composition comprising both MIC-1 and TGF-β with a reasonable expectation that the resultant composition would have a greater activity than either agent alone.

Conclusion

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO99/06445 discloses GDF-15 which although not identical to the protein of the instant application reads on the claims that are not dependent on the specific sequences. U.S.

Patent No. 6,524,802 discloses a protein referred to as GDF-14 which is identical to the process form of the instant GDF-15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.
Examiner
Art Unit 1636

JAMES KETTER
PRIMARY EXAMINER